

**REMARKS/ARGUMENTS****Claim Objections**

The Examiner objected to Claim 4 because the period was missing from the end. The Applicant has made appropriate correction.

**Claim Rejections - 35 U.S.C. 103**

The Examiner rejected claims 1, 2, 4-8, 10-14, 16-20 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over Becker et al. (U.S. Patent No. 6,712,757) in view of Kadan (U.S. Patent No. 6,419,654).

The Examiner stated: "In regard to claims 1, 4, 7, 10, 13 and 16, Becker et al. teach a sleeve 10 comprised of a cylinder 22 that received the outer tube of an endoscope 28 (see Figures 1 and 6). A docking member 24 including a cavity 50 to snugly receive the proximal end of the endoscope is mounted at the proximal end of cylinder 22 and has an internal means for communicating with the central bore in cylinder 22 (see Figure 1).

Docking member 24 also includes an annular groove 56 and an O-ring 59 for forming an air and water tight seal between the endoscope and the docking member 24 (see Figure 4). Becker et al. also teach fluid inlet port 12 and suction port 14 that are in communication with the central bore in cylinder 22 for irrigation and suction (see Figure 1). However, fluid inlet port 12 and suction port 14 are positioned on the cylinder 22, not the docking member 24. Kadan discloses a similar lavage system comprised of a handpiece 10 attached to a cannula 22 where handpiece 10 includes irrigation and suctioning channels 26 and 28 that are in communication with an internal means in handpiece 10 for providing irrigation and suction (see Figure 1). Kadan thus demonstrates that providing channels or ports for irrigation and suction on the proximal or handpiece portion of a lavage system is well known in the art. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to position the fluid inlet port 12 and suction port 14 of Becker et al. on the docking member 24, in the manner disclosed by Kadan.

In regard to claims 2, 8 and 14, Figure 7 of Becker et al. shows that, as broadly as claimed, the distal end of cylinder 22 is fenestrated. In regard to claims 5, 6, 11, 12, 17 and 18, Figure 1 of Becker et al. shows that docking member 24 comprised a hollow center. Furthermore, the fluid inlet port 12 and suction port 14, as placed in the position contemplated by Becker et al. in view of Kadan (above), would comprise peripheral bores for allowing fluid and suction to access the internal means of docking member 24 and the interior channel of cylinder 22.”

In regard to claims 1, 4, 7, 10, 13 and 16, the Becker et al. invention is intended for cleaning the window of an endoscope and producing a fluid spray for irrigating the body cavity. See Abstract; Figure 7; column 4, lines 46-61; and claim 1. The instant invention is intended for gastrointestinal lavage<sup>1</sup> with subsequent vacuuming of the lavage fluid (see page 15, lines 14-19; and page 10, lines 7-8). Claims 1, 7, 13 and 19 have been amended to make this clear.

Additional support for these amendments can be seen at page 17, line 19 to page 18, line 6.

Also, the Becker et al. invention is rigid (see column 3; lines 10-11) while the instant invention is flexible (see page 17, line 1). All claims except claim 13 reflect that the tube of the instant invention is flexible. Claim 13 has been amended to reflect this feature.

Additionally, the Becker et al. invention has two separate channels attached to the side of the cylinder. See column 3, lines 10-11; and Figures 2, 5 and 7. Fluid goes down one channel and is suctioned up through the other channel. See column 4, lines 46-61. In contrast, in the instant invention there is only one central bore 18 through the tube 14. See page 17, line 19 to page 18, line 6.

The above referenced amendments serve to distinguish the claims of instant invention from the Becker et al. invention.

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<sup>1</sup> Lavage means “A washing, especially of a hollow organ such as the stomach or lower bowel, with repeated injections of water.” *The American Heritage® Stedman’s Medical Dictionary* Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company.

While the Becker et al. and the instant invention are in the same field of medical examination and treatment, namely endoscopy, the Kadan invention is intended for application in the field of arthroscopy. Endoscopy comprises placing an instrument into a body cavity through an existing orifice. Example: examining and treating the stomach through the mouth. Arthroscopy comprises examination and treatment of the interior of a joint using an endoscope that is inserted into the joint through a small incision<sup>2</sup>.

The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination.<sup>3</sup>

The fact that the classification for the Kadan invention is US 604/27 and the classification of the Becker et al. invention is US 600/121 amply demonstrates that they are in non-analogous fields. An inventor in the field of endoscopy would not look to the field of arthroscopy for solution of his problems.

In regard to claims 2, 8 and 14, Applicant respectfully disagrees that Becker et al. shows any sort of fenestration. Fenestration means an opening in the surface of a structure, as in a membrane. The word comes from the Latin "fenestra", meaning window. All the openings 82 in the instant invention are in the side wall of the tube 14. See Figure 5. A side wall is clearly equivalent to a membrane. Thus they can properly be called fenestrations. Referring to Figure 2 of the Becker et al. invention, element 38 is called a hood. It is at the distal end of the fluid conduit 36. The other opening 32 is the distal end of the suction conduit. Both the openings in the Becker et al. invention are at the ends of tubes. Thus they are not placed in a membrane and cannot be fenestrations.

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<sup>2</sup> *The American Heritage® Stedman's Medical Dictionary Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company.*

<sup>3</sup> *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1443, 1446 (Fed. Cir. 1992)

The Applicant respectfully traverses the Examiner's rejection of claims 5, 6, 11, 12, 17 and 18. First, claims 5, 11 and 17 make no mention of hollow centers. All of them concern peripheral bores. Simple mention of an element of a claim in a prior art reference does not make that element obvious. The invention must be considered "as a whole"<sup>4</sup>. Claims 6, 12 and 18 are dependent and thus include all the limitations of the claims from which they depend. Therefore, these claims are not made obvious by mention of a hollow center in the Becker et al. patent.

#### Un-rejected claims

In the Office Action the Examiner has made no specific rejection with regard to claims 3, 9, 15 and 21, which cover the medial pleat element of this invention. In making a rejection for obviousness, an Examiner must: (a) cite the best references at his command; (b) cite the particular part of the reference relied on; and (c) explain the pertinence of each reference to each claim rejected<sup>5</sup>. In this Office Action, the Examiner has failed to cite any particular part of the references nor provide any comments with regard to claim 3, 9, 15 and 21. The Examiner has failed to meet his burden of presenting a prima facie case of obviousness with regard to these claims. Therefore these claims must be allowable. Since claim 3, 9, 15 and 21 depend from rejected claims, new claims 35-44 have been added. Claim 25 is a combination of claims 1 and 3. Claim 30 is a combination of claims 7 and 9. Claim 35 is a combination of claims 13 and 15. Claim 40 is a combination of claims 19 and 21. Claims 35-44 must be allowable.

#### Additional amendments

Applicant noted that there was no antecedent basis for the peripheral bores mentioned in claim 19 c) and d). Applicant replaced all references to "internal means" in claim 19 a) with mention of the peripheral bores. Support for this amendment can be seen in claim 5. No new matter has been added.

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<sup>4</sup> See 35 U.S.C. 103(a)

<sup>5</sup> 37 C.F.R. 1.104(c)(2)

## Conclusion

The Examiner stated: "The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant should note the following prior art reference disclosing an irrigation/suction sheath for an endoscope: Glowa et al., U.S. Patent No. 6,086,542."

Applicant has noted the prior art made of record and particularly the Glowa et al. reference but does not believe these affect the patentability of his invention.

An additional fee of \$356 is due on account of the above amendments. See attached Patent Application Fee Determination Record. A credit card authorization for this amount is enclosed. Reconsideration of this application and its early allowance are respectfully requested in view of the above presented amendments and remarks.

Respectfully submitted,



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